



## Complete Summary

---

### **GUIDELINE TITLE**

Screening of infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy: US Preventive Services Task Force recommendation statement.

### **BIBLIOGRAPHIC SOURCE(S)**

US Preventive Services Task Force (USPSTF). Screening of infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy: US Preventive Services Task Force recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2009. 10 p. [12 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

## **COMPLETE SUMMARY CONTENT**

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
EVIDENCE SUPPORTING THE RECOMMENDATIONS  
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS  
QUALIFYING STATEMENTS  
IMPLEMENTATION OF THE GUIDELINE  
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT  
CATEGORIES  
IDENTIFYING INFORMATION AND AVAILABILITY

## **SCOPE**

### **DISEASE/CONDITION(S)**

- Hyperbilirubinemia
- Chronic bilirubin encephalopathy

### **GUIDELINE CATEGORY**

Prevention  
Screening

### **CLINICAL SPECIALTY**

Family Practice  
Internal Medicine

Obstetrics and Gynecology  
Pediatrics  
Preventive Medicine

## **INTENDED USERS**

Advanced Practice Nurses  
Allied Health Personnel  
Health Care Providers  
Hospitals  
Nurses  
Physician Assistants  
Physicians

## **GUIDELINE OBJECTIVE(S)**

To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting evidence on the screening of infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy

## **TARGET POPULATION**

Healthy term or near-term infants ( $\geq 35$  weeks' gestational age)

## **INTERVENTIONS AND PRACTICES CONSIDERED**

Screening for hyperbilirubinemia using risk-factor assessment, measurement of bilirubin level (in serum or by transcutaneous estimation), or a combination of methods

## **MAJOR OUTCOMES CONSIDERED**

**Key Question 1:** Does screening using risk-factor assessment and/or bilirubin testing reduce the incidence of acute or chronic bilirubin encephalopathy?

**Key Question 2:** Does risk-factor assessment accurately identify infants who may benefit from bilirubin testing?

**Key Question 3:** Does bilirubin testing accurately identify infants who may benefit from phototherapy?

**Key Question 4:** What are the harms of screening?

**Key Question 5:** Does treatment reduce the risk of bilirubin encephalopathy in infants identified by screening?

**Key Question 6:** What are the harms of treatment with phototherapy?

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

**Note from the National Guideline Clearinghouse (NGC):** A systematic evidence review was prepared by the Tufts Evidence-Based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

#### Search Strategy

EPC staff searched Medline for studies published from September 2001 to August 2007, using Medical Subject Heading (MeSH) terms and keywords, such as "jaundice," "bilirubin," "hyperbilirubinemia," and "kernicterus". For additional studies, EPC staff examined the bibliographies in existing studies and also consulted the lead experts from the USPSTF.

#### Study Selection

EPC staff included experimental and observational studies with comparison groups (concurrent or historical comparison groups, or before-and-after comparison) in the review. For adverse events or other effects associated with phototherapy, case reports or case series were also included. As this is an update of a previous report conducted by EPC staff, the literature search of Medline was restricted to studies published after September of 2001 (search date of the previous report). Only English language studies published in peer-reviewed journals were included. Review articles, letter to the editors, or comments were excluded.

General inclusion criteria for the studies were:

*Study Design:* Experimental or observational studies

*Population:* Healthy term or near-term infants ( $\geq 35$  weeks' gestation) regardless of countries

*Intervention:* Screening for risk factors or serum bilirubin or transcutaneous bilirubin or combinations; phototherapy or exchange transfusion

*Setting:* Hospital, primary care office, home (for follow-up studies).

*Comparator:* No screening or different risk levels for developing hyperbilirubinemia defined by the screening programs; no phototherapy or exchange transfusion

*Outcomes:* Rates of acute or chronic bilirubin encephalopathy; rates of serum bilirubin ( $\geq 20, 25, 30$  mg/dL); risk for developing hyperbilirubinemia or undergoing phototherapy; health outcomes and adverse events related to phototherapy

**Note:** Refer to the Evidence Synthesis (see the "Availability of Companion Documents" field) for specific exclusion criteria for each Key Question.

## **NUMBER OF SOURCE DOCUMENTS**

The search yielded 742 abstracts, of which 646 were rejected after initial abstract screening using very broad inclusion/exclusion criteria. Ninety-six articles were retrieved for full text examination. Full-text screening using the formal criteria rejected an additional 79 articles.

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Expert Consensus

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

**Note from the National Guideline Clearinghouse (NGC):** A systematic evidence review was prepared by the Tufts Evidence-Based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

### **Data Extraction**

One reviewer initially screened abstracts for possible inclusion. This initial screening used very broad criteria to ensure that all potentially relevant abstracts were included (i.e., any human studies with any kind of screening or treatment of hyperbilirubinemia were included). A second person reviewed all the potentially relevant abstracts using the formal study inclusion/exclusion criteria. The full text of the eligible abstracts was retrieved and examined in detail. After full article evaluation, data from qualified studies were abstracted (see Appendix B in the Evidence Synthesis; refer to "Availability of Companion Documents" field). Items of interest extracted were: study setting, population, control, description of screening strategy, definitions of bilirubin encephalopathy and elevated bilirubin, and methods of analyses. Any adverse events or other effects from screening or phototherapy were also extracted.

## **Quality Assessment**

EPC staff assessed the quality using criteria developed by the USPSTF. Each paper was assigned a quality rating of "good," "fair," or "poor" by two reviewers. The criteria of quality assessment for primary studies included the randomization techniques, clear definitions of outcomes, and consideration for potential confounders in cohort studies, or intention-to-treat analysis for randomized controlled trials (RCTs). A third reviewer reviewed those studies in which the quality rating was discordant between the first two reviewers. Final grades in those studies were reached via consensus. Because of the wide variability in reporting of adverse events or other effects (e.g., temperature changes, sizes of nevi), the findings from those studies were summarized but the quality of those studies was not assessed.

## **Data Analysis and Presentation**

Because of dissimilarities in the identified studies, no quantitative synthesis (meta-analysis) was performed. EPC staff assessed the ability of risk factor scores, transcutaneous or early bilirubin testing, or combinations thereof (index tests) to identify infants with high total serum bilirubin (TSB) (i.e., above the 95th hour-specific percentile) and infants who may benefit from phototherapy (as defined in the individual studies). To this end, EPC staff calculated from each study the corresponding sensitivity and specificity pairs. Multiple sensitivity/specificity pairs may be calculated for studies that report different cutoffs for the index or reference tests.

EPC staff also characterized the diagnostic ability of each test using positive and negative likelihood ratios (LR+ and LR-, respectively). These quantities express the information conveyed by the test results. Briefly, LR+ quantifies the increase of the pre-test odds (e.g., identifying high TSB values when the screening test is positive). Conversely, LR- quantifies how much less likely a high TSB value is if the index test result is negative. LR+ and LR- values of 1 imply no diagnostic ability. By convention,  $LR+ > 10$  and  $LR- < 0.1$  imply informative and useful tests. Instead of providing tables of likelihood ratios per study and cutoff used, EPC staff integrated the relevant information in the figures.

EPC staff recorded and reported the area under the curve (AUC) value from receiver operating characteristic (ROC) curve analyses. AUC values close to 1 imply better diagnostic ability. AUC values of 0.5 mean that the diagnostic ability of a test is no better than chance.

Whenever possible, direct comparisons were made; otherwise qualitative indirect comparisons were performed.

Intercooled Stata 8.2 (Stata Corp., College Station, TX) was used for calculations and graphics.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Balance Sheets  
Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

**Table 1. U.S. Preventive Services Task Force Recommendation Grid\***

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

\*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist us in drawing conclusions (e.g., presence or absence of dose-response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that 1 of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med*. 2007;147:871-875.[5 references].

## **I Statements**

For I statements, the USPSTF has a new plan to commission its Evidence-based Practice Centers to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. *Ann Intern Med*. 2009;150:199-205.

[www.annals.org](http://www.annals.org)

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: For example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends in order to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.



Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice**

<b>Grade</b>	<b>Grade Definitions</b>	<b>Suggestions for Practice</b>
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if there are other considerations in support of the offering/providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

### **USPSTF Levels of Certainty Regarding Net Benefit**

**Definition:** The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> <li>• The number, size, or quality of individual studies</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice</li> <li>• Lack of coherence in the chain of evidence</li> </ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>• The limited number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Findings not generalizable to routine primary care practice</li> <li>• A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Comparison with Guidelines from Other Groups  
 External Peer Review  
 Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Peer Review. Before the U.S. Preventive Services Task Force makes its final determinations about recommendations on a given preventive service, the Evidence-Based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and

completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the final recommendations are confirmed.

Comparison with Guidelines from Other Groups. Recommendations for screening from the following groups were discussed: American Academy of Pediatrics and the Canadian Paediatric Society.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The US Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

#### Summary of Recommendation and Evidence

The USPSTF concludes that the evidence is insufficient to recommend screening infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy. **This is an I Statement.**

#### Clinical Considerations

#### Considerations for Practice When Evidence Is Insufficient

- Potential preventable burden: Severe neonatal hyperbilirubinemia is associated with kernicterus, the yellow staining of specific areas of brain tissue in the neonate caused by accumulation of unconjugated bilirubin. Chronic bilirubin encephalopathy describes the clinical neurologic sequelae associated with severe hyperbilirubinemia, including choreoathetoid cerebral palsy, sensorineural hearing loss, gaze paresis, and intellectual deficits. However, hyperbilirubinemia alone is not sufficient to account for these neurologic findings. Infants with extremely high levels of serum bilirubin but no apparent sequelae have been reported, and infants without documented high serum levels of bilirubin have been found to have kernicterus. As mentioned earlier, the United Kingdom (UK) incidence of bilirubin encephalopathy is estimated at 0.9 in 100,000 live births.
- Potential harms: Potential harms caused by interference with breastfeeding, disruption of maternal-infant bonding, pain caused by heel stick or venipuncture, weight loss, gastrointestinal problems, possible growth of melanocytic nevi, and labeling of infants that have elevated bilirubin levels are unmeasured but may be important.

- Costs: The monetary cost to provide universal screening would be very large, particularly if serum or transcutaneous bilirubin (TcB) measurement is adopted as a universal screening tool.
- Current practice: Universal screening with a variety of methods is widespread in the United States.

## **Patient Population Under Consideration**

This USPSTF recommendation addresses screening for hyperbilirubinemia to reduce the incidence of chronic bilirubin encephalopathy in healthy term or near-term infants ( $\geq 35$  weeks' gestational age).

## **Assessment of Risk**

Risk factors for hyperbilirubinemia include exclusive breastfeeding, family history of neonatal jaundice, bruising, cephalohematoma, ethnicity (Asian, black), maternal age ( $> 25$  years), male gender, glucose-6-phosphate dehydrogenase deficiency, and gestational age of  $< 38$  weeks. The contribution of these risk factors to chronic bilirubin encephalopathy in otherwise healthy children is not well understood.

## **Screening Tests**

Screening for hyperbilirubinemia may consist of risk-factor assessment, measurement of bilirubin level (either in serum or by transcutaneous estimation), or a combination of methods.

## **Treatment**

Phototherapy is commonly used to treat hyperbilirubinemia. A previous systematic review reported that one needs to treat 6 to 10 otherwise healthy jaundiced neonates with total serum bilirubin (TSB) levels of  $\geq 15$  mg/dL with phototherapy to prevent the TSB level in 1 additional infant from rising above 20 mg/dL.

Exchange transfusion is used to treat extreme hyperbilirubinemia. Although death as a complication of exchange transfusion is rare, significant morbidity (apnea, bradycardia, cyanosis, vasospasm, thrombosis, or necrotizing enterocolitis) occurs in as many as 5% of exchange transfusions, and the risks associated with the use of blood products must always be considered. Hypoxic-ischemic encephalopathy and acquired immune deficiency syndrome (AIDS) have occurred in otherwise healthy infants receiving exchange transfusions.

## **Definitions:**

## **What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice**

<b>Grade</b>	<b>Grade Definitions</b>	<b>Suggestions for Practice</b>
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.

Grade	Grade Definitions	Suggestions for Practice
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if there are other considerations in support of the offering/providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

### USPSTF Levels of Certainty Regarding Net Benefit

**Definition:** The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> <li>• The number, size, or quality of individual studies</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice</li> </ul>

Level of Certainty	Description
	<ul style="list-style-type: none"> <li>Lack of coherence in the chain of evidence</li> </ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>The limited number or size of studies</li> <li>Important flaws in study design or methods</li> <li>Inconsistency of findings across individual studies</li> <li>Gaps in the chain of evidence</li> <li>Findings not generalizable to routine primary care practice</li> <li>A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## CLINICAL ALGORITHM(S)

None available

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

#### Benefits of Detection and Early Intervention

Early treatment can decrease the number of infants with elevated serum bilirubin levels. However, the U.S. Preventive Services Task Force (USPSTF) found inadequate evidence that treating elevated bilirubin levels in term or near-term infants to prevent severe hyperbilirubinemia resulted in the prevention of chronic bilirubin encephalopathy.

### POTENTIAL HARMS

#### Harms of Detection and Early Treatment

Hyperbilirubinemia is commonly treated with phototherapy, and severe hyperbilirubinemia may be treated with exchange blood transfusion. The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence regarding

the harms of phototherapy. Potential harms of phototherapy include weight loss, gastrointestinal problems, interruption of breastfeeding and disruption of the maternal-infant relationship, and possibly growth of melanocytic nevi. Significant morbidity (apnea, bradycardia, cyanosis, vasospasm, thrombosis, necrotizing enterocolitis) occurs in as many as 5% of patients who undergo exchange transfusion.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.
- Recommendations are based on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.
- The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policy-makers should understand the evidence but individualize decision making to the specific patient or situation.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its [Web site](#). The combination of electronic access and extensive material in the

public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

## **IMPLEMENTATION TOOLS**

Personal Digital Assistant (PDA) Downloads  
Pocket Guide/Reference Cards

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Staying Healthy

### **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

US Preventive Services Task Force (USPSTF). Screening of infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy: US Preventive Services Task Force recommendation statement. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2009. 10 p. [12 references]

### **ADAPTATION**



Not applicable: The guideline was not adapted from another source.

**DATE RELEASED**

2009 Oct

**GUIDELINE DEVELOPER(S)**

United States Preventive Services Task Force - Independent Expert Panel

**GUIDELINE DEVELOPER COMMENT**

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

**SOURCE(S) OF FUNDING**

United States Government

**GUIDELINE COMMITTEE**

U.S. Preventive Services Task Force (USPSTF)

**COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Task Force Members\**: Ned Calonge, MD, MPH, *Chair*, USPSTF (Colorado Department of Public Health and Environment, Denver, CO); Diana B. Petitti, MD, MPH, *Vice-Chair*, USPSTF (Arizona State University, Phoenix, AZ); Thomas G. DeWitt, MD (Children's Hospital Medical Center, Cincinnati, OH); Allen J. Dietrich, MD (Dartmouth Medical School, Lebanon, NH); Kimberly D. Gregory, MD, MPH (Cedars-Sinai Medical Center, Los Angeles, CA); Russell Harris, MD, MPH (University of North Carolina School of Medicine, Chapel Hill, NC); George J. Isham, MD, MS (HealthPartners, Minneapolis, MN); Michael L. LeFevre, MD, MSPH (University of Missouri School of Medicine, Columbia, MO); Rosanne M. Leipzig, MD, PhD (Mount Sinai School of Medicine, New York, NY); Carol Loveland-Cherry, PhD, RN (University of Michigan School of Nursing, Ann Arbor, MI); Lucy N. Marion, PhD, RN (School of Nursing, Medical College of Georgia, Augusta, GA); Bernadette Melnyk, PhD, RN (Arizona State University College of Nursing & Health Innovation, Phoenix, AZ); Virginia A. Moyer, MD, MPH (Baylor College of Medicine, Houston, TX); Judith K. Ockene, PhD (University of Massachusetts Medical School, Worcester, MA); George F. Sawaya, MD (University of California, San Francisco, CA); Barbara P. Yawn, MD, MSPH, MSc (Olmsted Medical Center, Rochester, MN)

\*Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to [www.ahrq.gov/clinic/uspstfab.htm](http://www.ahrq.gov/clinic/uspstfab.htm).

**FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. Task Force members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#).

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to <http://www.ahrq.gov/news/pubsix.htm> or call 1-800-358-9295 (U.S. only).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

Evidence Reviews:

- Trikalinos T, Chung M, Lau J, Ip S. Systematic review of screening for bilirubin encephalopathy in neonates. Pediatrics 2009 124(4):1162-71. Electronic copies: Available from the [U.S. Preventive Services Task Force Web site](#).
- Ip S, Chung M, Trikalinos T, DeVine D, Lau J. Screening for bilirubin encephalopathy. Evidence synthesis No. 72. AHRQ Publication No. 09-05136-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality, October 2009. Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#).

The following is also available:

- Screening of infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy: clinical summary of the U.S. Preventive Services Task Force recommendation. 2009. 1 p. Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#).

Background Articles:

- Barton M et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med. 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med. 2007;147:117-122. [2 references]

- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-875. [5 references].
- Petitti DB, Teutsch SM, Barton MB, Sawaya GF, Ockene JK, DeWitt T. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205.

Electronic copies: Available from [U.S. Preventive Services Task Force \(USPSTF\) Web site](#).

The following is also available:

- The guide to clinical preventive services, 2008. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2009. 284 p. Electronic copies available from the [AHRQ Web site](#). See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#).

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to <http://www.ahrq.gov/news/pubsix.htm> or call 1-800-358-9295 (U.S. only).

The [Electronic Preventive Services Selector \(ePSS\)](#), available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI Institute on September 18, 2009. The information was verified by the guideline developer on October 19, 2009.

## **COPYRIGHT STATEMENT**

Requests regarding copyright should be sent to: Randie Siegel, Associate Director, Office of Communications and Knowledge Transfer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, email: [info@ahrq.gov](mailto:info@ahrq.gov).

[Copyright/Permission Requests](#)

Date Modified: 12/7/2009

